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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,567	11/24/2003	Yin-Chun Huang	030113	1877

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BERKELEY LAW & TECHNOLOGY GROUP
1700NW 167TH PLACE
SUITE 240
BEAVERTON, OR 97006

EXAMINER

PUNNOOSE, ROY M

ART UNIT PAPER NUMBER

2877

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/718,567	Applicant(s) HUANG ET AL.	
	Examiner Roy M. Punnoose	Art Unit 2877	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-16 and 18-20 is/are rejected.
- 7) ☒ Claim(s) 8 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

2. Claims 1 and 12 are objected to for the following reason: The words “with” and “comprising” in the preamble has the same meaning and therefore it duplicates the point light source and the lens that are recited in the body of said claims. It creates doubt whether the point light source and the lens in the body of the claims are the same as the ones recited in the preamble, or if they are different and/or additional point light source and lens. For examination purposes it is assumed that the point light source and lens in the body of the claims is the same as the ones recited in the preamble of the respective claims. Appropriate correction is required.
3. Claim 4 is objected to because the recitation “point light source *includes* a light emitting diode” gives the perception that there are other sources of light in the apparatus and that said light emitting diode is one among a plurality of light sources. For examination purposes it is assumed that the “point light source *is* a light emitting diode.” Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 10 and 19 provides for the use of a test strip for monitoring a concentration of glucose in a blood sample, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim

Art Unit: 2877

is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 10 and 19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

6. Claims 11 and 20 provides for the use of a test strip for monitoring a concentration of cholesterol in a blood sample, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 11 and 20 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections

7. In the specification of the instant application, the following is disclosed on page 6:

“The present apparatus can be used as a reflectance instrument for detecting a small-size object or a small target area of an object. A content of a specific component contained in the object thus can be determined in accordance with the reflectance of the light reflected from the object detected by the present apparatus. The present apparatus can be used to detect the reflectance of a light reflected from a colored area of a test strip occurring due to contact with a tested solution. A content of a specific component of the tested solution

Art Unit: 2877

can be determined in accordance with the reflectance of the light reflected the colored area of the test strip.”

It is evident from applicant’s disclosure above that the claims of the instant application cover a wide array of areas such as object detection, reflectance measurement, color measurement, etc. It should be noted that the prior art from all relevant fields are applied to reject claims is based on applicant’s disclosure above.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claims 1-4, 6, 12-13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Roussel (US_4,283,146).**

With regard to claims 1-4, 6, 12-13 and 15, Roussel discloses an apparatus (see Figures 1 and 2) with a combination of a point light source and a single lens, comprising: a point light source/LED 1 (see col.2, line 35), a photodetector 7, and a lens 8, positioned in the same side of said point light source 1 and said photodetector 7 in order that a light emitting from said point light source 1 is focused onto a target area 8’ of an object through said lens 8, and a reflected light from said target area 8’ of said object is focused onto said photodetector 7 through said lens 8 (see col.2, lines 33 – col.6, line 43, and specifically col.2, lines 33-64), a holder 20 for holding said point light source at a first end (the first end being the left half of the holder 20 in Figures 1 and 2), and holding said photodetector at a second end (the second end being the right half of the holder 20 in Figures 1 and 2), said first end and said second end formed on the same side of said

Art Unit: 2877

holder 20 (see Figure 1), wherein said object is placed at a focal position 8' of said lens 8 (see col.2, lines 63-64) and the photodetector is a photodiode 7 (see col.2, lines 40-42).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 5, 7, 9-10, 14, 16 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roussel (US_4,283,146) in view of Phillips et al (US_5,059,394).

12. Claims 5 and 14 are rejected because:

- A. Roussel teaches all claim limitations as disclosed above and further teaches detecting/measuring reflectance and/or color (see col.6, lines 14-23) with an apparatus for detecting a small-size object or a small target area on said object for quantification of said object's light reflective characteristics from which other characteristics such as color or substance or the content of the object or the target area can be determined.
- B. However, Roussel does not explicitly teach that the photodetector generates a response current in response to reflected light from a target area of an object in an apparatus for detecting a small-size object or a small target area on said object for quantification said object's light reflective characteristics from which other characteristics such as color or substance or the content of the object or the target area can be determined.

Art Unit: 2877

- C. Phillips et al (Phillips hereinafter) discloses an apparatus in which the photodetector generates a response current in response to reflected light (see col.7, lines 48-61, and particularly lines 57-59) from a target area 14 of an object 12 (see col.5, lines 38-41 and Figure 1), said apparatus for quantification of light reflective characteristics of said target area on the object from which other characteristics such as color or substance or the content of the object or the target area can be determined.
- D. In view of Phillips' teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate generating a response current in response to reflected light from a target area of an object into Roussel's apparatus due to the fact that such incorporation would provide a more accurate apparatus for detecting a small-size object or a small target area on an object because current driven circuits are less susceptible to noise from the immediate surroundings of said apparatus for quantification the object's light reflective characteristics, from which other characteristics such as color or substance or the content of the object or the target area can be determined.
13. Claims 7 and 16 are rejected for the same rational for rejecting claims 1 and 12 above, and additionally because:
- A. Roussel teaches all claim limitations as disclosed above and further teaches detecting/measuring reflectance and/or color (see col.6, lines 14-23) with an apparatus for detecting a small-size object or a small target area on said object for quantification of said object's light reflective characteristics from which other characteristics such as color or substance or the content of the object or the target area can be determined.

- B. However, Roussel does not teach of an object which includes a test strip having a light-absorbing area occurring in response to a specific component of a tested solution contacting therewith and capable of absorbing light emitting from a point light source, in an apparatus for detecting a small target area on said object for quantification of said object's light reflective characteristics from which other characteristics such as color or substance or the content of the object or the target area can be determined.
- C. Phillips discloses an apparatus/system comprising an object/test strip 12 having a light-absorbing area 14 occurring in response to a specific component of a tested solution contacting therewith and capable of absorbing light emitting from a point light source/LED (see abstract, col.3, line 24 – col.21, line 43, and specifically col.7, lines 48-53 and col.10, lines 30-68), in an apparatus for detecting a small target area on said object for quantification of said object's light reflective characteristics from which other characteristics such as color or substance or the content of the object or the target area can be determined.
- D. In view of Phillips' teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate an object which includes a test strip having a light-absorbing area occurring in response to a specific component of a tested solution contacting therewith and capable of absorbing light emitting from a point light source into Roussel's apparatus due to the fact that such incorporation would provide an apparatus with more measurement/detection functions for measuring/detecting a small-size object or a small target area on an object for quantification of said object's light

Art Unit: 2877

reflective characteristics from which other characteristics such as color or substance or the content of the object or the target area can be determined.

14. Claims 9, 10, 18 and 19 are rejected for the same rational for rejecting claims 1, 7, 12 and 16 above, and additionally because:

- A. Roussel teaches all claim limitations as disclosed above and further teaches detecting/measuring reflectance and/or color (see col.6, lines 14-23) with an apparatus for detecting a small-size object or a small target area on said object for quantification of said object's light reflective characteristics from which other characteristics such as color or substance or the content of the object or the target area can be determined.
- B. However, Roussel does not teach of a specific component of a tested solution to be detected depends on an enzyme system contained in a test strip and that the test strip is used for monitoring a concentration of glucose in a blood sample in an apparatus for detecting a small target area on an object for quantification of said object's/target area's light reflective characteristics from which other characteristics such as color or substance or the content of the object or the target area can be determined.
- C. Phillips discloses that a specific component of a tested solution to be detected depends on an enzyme system contained in a test strip and that the test strip is used for monitoring a concentration of glucose in a blood sample (see col.3, lines 44-54; col.8, lines 51-55 and specifically lines 54-55) in an apparatus for detecting a small target area on an object for quantification of said object's/target area's light reflective characteristics from which other characteristics such as color or substance or the content of the object or the target area can be determined.

Art Unit: 2877

D. In view of Phillips' teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate detecting a specific component of a tested solution wherein detection depends on an enzyme system contained in a test strip and that the test strip is used for monitoring a concentration of glucose in a blood sample into Roussel's apparatus due to the fact that such incorporation would provide an apparatus with more measurement/detection functions for detecting a small target area on an object for quantification of said object's/target area's light reflective characteristics from which other characteristics such as color or substance or the content of the object or the target area can be determined.

15. **Claims 11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roussel (US_4,283,146) in view of Phillips et al (US_5,059,394) and further in view of Markart et al (US_5,281,395).**

16. Claims 11 and 20 are rejected for the same rational for rejecting claims 1, 7, 9, 12, 16 and 18 above, and additionally because:

- A. Roussel and Phillips teach all claim limitations as disclosed above.
- B. However, Roussel and Phillips do not teach of a test strip that is used for monitoring a concentration of cholesterol in a blood sample in an apparatus for detecting a small target area on an object for quantification of said object's/target area's light reflective characteristics from which other characteristics such as color or substance or the content of the object or the target area can be determined.
- C. Markart et al (Markart hereinafter) teaches prior art disclosure of a test strip that is used for monitoring a concentration of cholesterol in a blood sample (see col.1, lines 45-53

Art Unit: 2877

and specifically lines 47 and 50) in an apparatus for detecting a small target area on an object for quantification of said object's/target area's light reflective characteristics from which other characteristics such as color or substance or the content of the object or the target area can be determined.

- D. In view of Markart's teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate an object having a test strip that is used for monitoring a concentration of cholesterol in a blood sample into Roussel's apparatus due to the fact that such incorporation would provide an apparatus with more measurement/detection functions for detecting a small target area on an object for quantification of said object's/target area's light reflective characteristics from which other characteristics such as color or substance or the content of the object or the target area can be determined.

Allowable Subject Matter

17. Claims 8 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, or, if the rejection of the base/parent claim(s) can be overcome.

18. Claims 8 and 17 are allowable because the prior art of record, taken alone or in combination, fails to disclose or render obvious an apparatus in which sampling amount of tested solution is determined in accordance with the reflectance of light with the first wavelength from a light-absorbing area, and light with the second wavelength absorbed by said light-absorbing area occurring in response to a specific component of said tested solution, wherein a content of said specific component is determined in accordance with the reflectance of said light with the

Art Unit: 2877

second wavelength from said light-absorbing area, in combination with the rest of the limitations of the respective claims, inclusive of the limitations of all parent claims.

Contact/Status Information

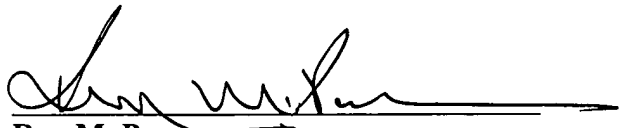
19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Roy M. Punnoose** whose telephone number is **571-272-2427**.

The examiner can normally be reached on 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gregory J. Toatley, Jr.** can be reached on **571-272-2800 ext.77**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 07, 2006


Roy M. Punnoose
Patent Examiner
Art Unit 2877